WebMD

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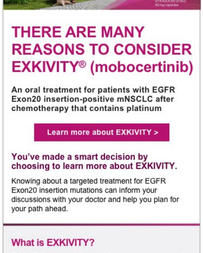

THERE ARE MANY REASONS TO CONSIDER EXKIVITY® (mobocertinib)

An oral treatment for patients with EGFR Exon20 insertion-positive mNSCLC after chemotherapy that contains platinum

Learn more about EXKIVITY >

You've made a smart decision by choosing to learn more about EXKIVITY.

Knowing about a targeted treatment for EGFR Exon20 insertion mutations can inform your discussions with your doctor and help you plan for your path ahead.

What is EXKIVITY?

EXKIVITY is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):

- that has spread to other parts of the body (metastatic) and cannot be removed by surgery, **and**
- has a certain abnormal epidermal growth factor receptor (EGFR) gene, **and**
- whose disease has worsened while on or after chemotherapy that contains platinum

Your healthcare provider will perform a test to make sure that EXKIVITY is right for you.

It is not known if EXKIVITY is safe and effective in children.

EXKIVITY is approved based on a medical study that measured how many people responded to treatment and for how long. There are ongoing studies to confirm its continued approval.

EXKIVITY may cause serious side effects, including changes in the electrical activity of your heart, lung problems, heart problems, including heart failure, and diarrhea.

AN ORAL TREATMENT THAT FITS YOUR SCHEDULE

Take 4 pills at the same time each day, with or without food

Find out more about dosing >

CLINICAL RESULTS WITH EXKIVITY

EXKIVITY was shown to help in a clinical study

The risks and benefits of EXKIVITY were studied in 114 adults with metastatic NSCLC who had EGFR Exon20 insertion mutations. All people had been previously treated with chemotherapy containing platinum.

The most common side effects seen in the EXKIVITY clinical study included diarrhea, rash, nausea, mouth sores, vomiting, decreased appetite, infection of skin around nails, tiredness, dry skin, and muscle or bone pain.

EXKIVITY **shrank tumors by about a third** or more for approximately

3 in 10 people

with a median length of response of

17.5 months

- Meaning, half of the people who responded to EXKIVITY did so for 17.5 months or longer and half responded for less than 17.5 months
- Approximately 60% of the people who responded to EXKIVITY did so for 6 months or longer

In this study, it was likely that the majority of people who responded to EXKIVITY saw a response that lasted anywhere between 7.4 months and 20.3 months.

See the study results >

Use these tools to help talk to your doctor >

The treatment decisions you make now help determine your path forward. **At your next visit, talk to your doctor about the clinical trials of EXKIVITY to see if it's right for you.**

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about EXKIVITY?

EXKIVITY may cause serious side effects, including changes in the electrical activity of your heart called QTc prolongation and Torsades de Pointes. QTc prolongation can cause irregular heartbeats that can be life-threatening and may lead to death. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) and do blood tests to check your electrolytes before starting treatment and during treatment with EXKIVITY. Tell your healthcare provider right away if you feel dizzy, lightheaded, faint, or have an irregular heartbeat.

EXKIVITY may cause serious side effects, including:

- **Lung problems.** EXKIVITY may cause severe lung problems that may lead to death. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you develop any new or worsening symptoms, including trouble breathing or shortness of breath, cough, chest pain, or fever.
- **Heart problems, including heart failure.** EXKIVITY may cause heart problems that may lead to death. Your healthcare provider should check your heart function before you start and during treatment with EXKIVITY. Tell your healthcare provider right away if you have any signs or symptoms of a heart problem, including feeling like your heart is pounding or racing, shortness of breath, chest pain, swelling of your ankles and feet, or feeling faint.
- **Diarrhea.** Diarrhea is common during treatment with EXKIVITY and may sometimes be severe. Severe diarrhea can cause you to lose too much body fluid (dehydration) and kidney problems. Your healthcare provider may tell you to start drinking more fluids and electrolytes to replace body salts or start taking your antidiarrheal medicines. Tell your healthcare provider right away if you have any loose stools or have stools more often than is normal for you.

The most common side effects of EXKIVITY include diarrhea, rash, nausea, mouth sores, vomiting, decreased appetite, infection of skin around nails, tiredness, dry skin, muscle or bone pain. EXKIVITY may affect fertility in females and males, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of EXKIVITY. Call your doctor for medical advice about side effects. You may report side effects to FDA at **1-800-FDA-1088**.

Before taking EXKIVITY, tell your healthcare provider about all your medical conditions, including if you:

- have heart problems, including a condition called long QTc syndrome
- have problems with your electrolytes, such as sodium, potassium, calcium or magnesium
- have lung or breathing problems other than lung cancer
- are pregnant or plan to become pregnant. EXKIVITY can harm your unborn baby.

  Females who are able to become pregnant:
  - Your healthcare provider should do a pregnancy test before you start treatment with EXKIVITY. You should use an effective form of non-hormonal birth control during treatment and for **1 month** after your last dose of EXKIVITY. Birth control pills (oral contraceptives) and other hormonal forms of birth control may not work as well during treatment with EXKIVITY. Talk to your healthcare provider about birth control methods that might be right for you during this time. Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with EXKIVITY.

  Males who have female partners who are able to become pregnant:
  - You should use effective birth control during treatment and for **1 week** after your last dose of EXKIVITY.
- are breastfeeding or plan to breastfeed. It is not known if EXKIVITY passes into your breast milk. Do not breastfeed during treatment with EXKIVITY and for **1 week** after your last dose of EXKIVITY.

Tell your healthcare provider about all the medicines you take, including prescription medicines and over-the-counter medicines, vitamins, and herbal supplements. Tell your healthcare provider if you take medicines for heart problems. EXKIVITY and other medicines may affect each other causing serious side effects.

How should I take EXKIVITY?

- Take EXKIVITY exactly as your healthcare provider tells you to take it.
- Take your prescribed dose of EXKIVITY 1 time each day.
- Take EXKIVITY with or without food.
- Swallow EXKIVITY capsules whole. Do not open, chew, or dissolve the contents of the capsules.
- **Do not** change your dose or stop taking EXKIVITY unless your healthcare provider tells you to.
- Your healthcare provider may change your dose, temporarily stop, or permanently stop treatment with EXKIVITY if you develop certain side effects.
- If you miss a dose of EXKIVITY, and it has been more than 6 hours, skip the dose and take your next dose at your regularly scheduled time the next day.
- If you vomit a dose of EXKIVITY, do not take an extra dose. Take your next dose at your regularly scheduled time the next day.

What should I avoid while taking EXKIVITY?

- Avoid eating grapefruit or drinking grapefruit juice during treatment with EXKIVITY. Grapefruit may increase the amount of EXKIVITY in your blood.

Please see Patient Information in the EXKIVITY (mobocertinib) full Prescribing Information.

EXKIVITY® mobocertinib 40 mg capsules

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